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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,081	03/31/2006	Yacta Endo	3190-091	1222
33432 7590 04/01/2008 KILYK & BOWERSOX, P.L.L.C. 400 HOLIDAY COURT SUITE 102 WARRENTON, VA 20186				
EXAMINER				
MOSHER, MARY				
ART UNIT		PAPER NUMBER		
1648				
MAIL DATE		DELIVERY MODE		
04/01/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/571,081

**Applicant(s)**

ENDO ET AL.

**Examiner**

Mary E. Mosher, Ph.D.

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 8-10 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) 13-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-10, 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 13-20 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/20/2007.

This application contains claims 13-20 drawn to an invention nonelected with traverse in the reply filed on 8/20/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Response to Amendment***

Applicant has amended claim 1 to incorporate the limitations of both original claim 7 and original claim 11. In response to this amendment, the rejections of record are withdrawn except for claim 9. New rejections are presented below.

### ***Claim Objections***

Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 now limits the bioactive protein to an RNA polymerase, a DNA polymerase, a helicase, a coat protein, or a capsid protein. The protease protein of claim 9 is now outside the scope of parent claim 1.

***Claim Rejections - 35 USC § 112***

Claims 1-6, 8, 10, 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining reactivity to a drug by inhibiting or terminating transcription or translation or by measuring the biological activity of a polymerase or helicase, does not reasonably provide enablement for determining autodigestion or folding, or for determining bioactivity of capsid or coat proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification fails to teach RNA polymerase, DNA polymerase, helicase, coat proteins, or capsid proteins which autodigest. Also, in regard to folding, the specification suggests detecting a change in tertiary structure using NMR and CD or reactivity with a monoclonal or single chain antibody. However, a large quantity of experimentation would be required to purify normally folded proteins and determine the NMR or CD spectra or obtain tertiary-structure specific monoclonal antibodies, for the full range of proteins in the claimed method. Also, the specification fails to teach substrate recognition for coat and capsid proteins. Considering that the prior art teaches routine measurement of inhibition of transcription or translation of proteins and measurement of enzymatic activity of polymerase and helicase proteins, these embodiments of the invention would not require undue experimentation. However, considering the scope of the claims, the limited teachings in the specification, the quantity of experimentation required, the absence of working examples for autodigestion or folding for the proteins now claimed, and the state of the art, it is

concluded that undue experimentation would be required to enable the full scope of the invention as now claimed.

***Claim Rejections - 35 USC § 103***

Claims 1, 3, 5, 6, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenten et al US 2003/0207290 in view of Endo et al WO 03/064671. As discussed in the previous action, Kenten teaches an assay using in vitro transcription and translation, suggests using the same assay for identifying modulators of activity, discusses activities of proteases, polymerases, and helicases, and suggests use of wheat germ extracts. This differs from the amended claims in that Kenten does not discuss wheat germ extracts with endosperm and a low molecular weight synthesis inhibitor is removed. However, Endo teaches a wheat germ extract with substantial removal of endosperm and low molecular weight inhibitors, which has the advantages of high stability and high efficiency. Therefore it would have been prima facie obvious to carry out the suggestions made by Kenten using the wheat germ extract taught by Endo, with reasonable expectation of success.

Claim 9 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Heinz et al (Antimicrobial Agents and Chemotherapy 40:267-270, 1996, in IDS) in view of Endo et al (WO 03/064671, in IDS), for reasons of record. Although parent claim 1 has been amended to incorporate limitations which are not taught or suggested by these references, claim 9 is outside the scope of amended claim 1, as discussed above. Since claim 9 is still drawn to a method involving a protease, the rejection remains applicable.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher, Ph.D./  
Primary Examiner, Art Unit 1648

3/27/08